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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/868,889	09/14/2001	Jon Hangeland	102241-101	6789

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EXAMINER	
COPPINS, JANET L	
ART UNIT	**PAPER NUMBER**
1625	

DATE MAILED: 02/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/868,889	HANGELAND ET AL.	
	Examiner	Art Unit	
	Janet Coppins	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14,17-24 and 27-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,5-14,17-24 and 27-29* is/are rejected.

7)☒ Claim(s) *3,4* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 9.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-29 pending in the instant application

Response to Amendment

1. Receipt is acknowledged of Applicants' Amendment "B" and Response, submitted October 7, 2003, which has been received by the Examiner and entered of record in the file as paper no. 11. Accordingly, claims 15, 16, 25, and 26 are cancelled, and claims 23 and 29 are amended. Therefore, claims 1-14, 17-24, and 27-29 are now pending.

Information Disclosure Statement

2. Receipt is acknowledged of Applicants' Information Disclosure Statement, submitted August 15, 2003, which is in compliance with 37 CFR 1.97. Accordingly, the IDS has been considered by the Examiner and entered of record in the file as paper no. 9.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. The Examiner had previously rejected claims 23, 24, and 28 under 35 U.S.C. 112, first paragraph, as not being enabled. In view of the Applicants' amendatory changes to the claims, the issue of enablement has been overcome and the Examiner withdraws the enablement rejections from claims 23, 24, and 28.

5. However, claim 23 newly rejected under 35 U.S.C. 112, first paragraph, as being a reach-through claim. The claim is directed to a method for treating a disease associated with metabolism dysfunction, or which is dependent on the expression of a T_3 regulated gene, yet this

claim does not meet the requirements for "how to use" under 35 U.S.C. 112, first paragraph, and 35 U.S.C. 101, as stated below. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

6. Claim 29 also rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for compounds according to formula (I) for treating certain skin disorders or diseases, does not reasonably provide enablement for compounds that can treat *any* or *all* skin disorders or diseases. In In re Wands, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. § 112, first paragraph, have been described. They are:

1. the nature of the invention,
2. the state of the prior art,
3. the predictability or lack thereof in the art,
4. the amount of direction or guidance present,
5. the presence or absence of working examples,
6. the breadth of the claims,
7. the quantity of experimentation needed, and
8. the level of the skill in the art.

In the instant case, applicants are claiming a method of treating skin disorder or disease. The nature of the invention is of a compound of claim 1 for the treatment of a "skin disorder or disease" combined with a retinoid or vitamin D analog. As stated, however, the claim broadly recites that any or all skin disorders or diseases are intended. The state of the art does not teach any one compound for the absolute treatment of all skin disorders and diseases. Thus any claim to the broad treatment of all skin disorders/diseases is highly unpredictable given the current state of the art. Because neither the prior art nor the current application provide sufficient guidance to one of ordinary skill in the art as to the universal treatment of all skin disorders or

diseases utilizing the instant claimed compound, the quantity of experimentation for such a claim is considered to be undue and thus, not enabled. The Examiner suggests incorporating the diseases and disorders listed in claim 28 in order to overcome the rejection.

7. Claim 29 also rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Claim 29 is directed to a method of treating a skin disorder or disease by administering to a patient a therapeutically effective amount of a compound of claim 1 in combination with a retinoid or a vitamin D analog. The specification, however, does not provide any guidance as to the intended retinoid or vitamin D analog (please refer to page 14, lines 26-27).

Claim Rejections - 35 USC § 101

8. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

9. Claims 25, 26, and 29 previously rejected under 35 U.S.C. 101 as being improper product-use claims since they are drafted in terms of "use," which is not one of the statutory classes of invention. Applicants have cancelled claims 25 and 26 and amended claim 29, therefore the rejections have been overcome.

10. However, claim 23 rejected under 35 U.S.C. 101 as being a reach-through claim, because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility. The claimed method of treating diseases associated with metabolism dysfunction or dependent on gene expression does not comply with the utility requirement since

there is no disclosed pharmaceutical use, i.e. a method of treating a disease "dependent on the expression of a T_3 regulated gene" is not equivalent to a positive recitation of how to use the product for the treatment of a particular disease of real world relevance. The Examiner suggests incorporating some of the specific diseases that Applicants are enabled for treating in the specification.

Double Patenting

11. Claims 1, 2, 5-14, 19-24 and 27-29 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over U.S. 6,395,784. Applicants have traversed the rejection, arguing that in a double-patenting rejection, the application and patent must be commonly owned, and therefore the pending rejection is improper.

12. The Examiner respectfully disagrees, and directs the Applicants' attention to MPEP 804, page 800-16, Chart II-B: Conflicting Claims between an Application and a Patent: wherein the inventions are not patentably distinct, and there is **At least One Common Inventor, No Common Assignee**: the Examiner is directed to make an Obviousness-type Double Patenting rejection under 8.33 & 8.34 or 8.36, AND a rejection under 102(e)/103(a) AND a rejection under 102(f)/103(a) or 102(g)/103(a). The 6,395,784 patent lists Denis E. Ryono of Princeton, NJ as a sole inventor, who is also listed as an inventor in the instant application. Therefore the Examiner maintains the obviousness-type double patenting rejection and adds the following rejections under 35 U.S.C., 102 and 103:

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(f) he did not himself invent the subject matter sought to be patented.

14. Claims 1, 2, 5-14, 19-24 and 27-29 rejected under 35 U.S.C. 102(e) as being anticipated by Ryono, Denis, U.S. Pat. No. 6,395,784. The '784 patent discloses and recites thyroid receptor ligands according to formula (I) of column 3, and preferred compounds listed in columns 6-7, which read directly on the elected species of compounds of the instant invention (compounds wherein R_4= carboxylic acid amide).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

15. Claims 1, 2, 5-14,19-24 and 27-29 also rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter. The subject matter of the instant invention, thyroid receptor ligands according to the formula of claim 1, was invented by Denis Ryono and patented in U.S. Pat. No. 6,395,784.

Claim Rejections - 35 USC § 103

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

17. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

18. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

19. Claims 1, 2, 5-14, 17-24 and 27-29 rejected under 35 U.S.C. 103(a) as being obvious over Ryono, Denis U.S. 6,395,784.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of

invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Applicant is claiming the following compound and process:

Thyroid receptor ligand compounds consisting of a phenoxy-benzoyl structure linked to a carboxylic acid amide, pharmaceutical compositions containing them and methods of using them to treat diseases associated with metabolism dysfunction or dependent on the expression of a T3 regulated gene, such as obesity, hypercholesterolemia, atherosclerosis, osteoporosis, thyroid cancer, glaucoma, cardiac arrhythmia, congestive heart failure, etc.

Determination of the scope and content of the prior art (MPEP §2141.01)

The '784 patent teaches and recites thyroid receptor ligands according to formula (I) in column 3 and preferred compounds, including phenoxy-benzoyl-carboxylic acid amid compounds in columns 6 and 7. The '784 patent also discloses and recites pharmaceutical compositions and methods of using the compounds for treating diseases associated with

metabolism dysfunction or dependent on the expression of a T3 regulated gene, including the same diseases as listed above and instantly claimed.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The compounds of the instant invention and the conflicting claims of the reference patent differ in that the formula of instant claim 1 is not identical to the recited formula in claim 1 of the '784 patent, since the instant claim 1 is broader in scope than the claims of the reference patent (i.e. the '784 patent claims are specifically directed to phenoxy-benzoyl compounds with a carboxylic acid amide side-chain).

Finding of prima facie obviousness--rational and motivation (MPEP §2142-2413)

To those skilled in chemical art, the instant elected group of thyroid receptor compounds is not such an advance over the genus of compounds previously patented in the '784 reference, as requires invention, because chemists knowing the properties of the thyroid receptor ligands already patented would know what to expect in a genus of compounds that encompasses the patented compounds. The instant claimed compounds would have been obvious because one skilled in the art would have been motivated to prepare the compounds taught in the reference with the expectation of obtaining compounds which could be used for treating the same diseases associated with metabolism dysfunction or dependent on the expression of a T3 regulated gene. It would have been prima facie obvious to employ the formula claim 1 of the '784 patent, particularly when Applicants' elected Group IV, carboxylic acid amides, are taught as preferred compounds and specifically claimed in the reference patent. Therefore, the instant claimed compounds would have been suggested to one skilled in the art.

Claim Objections

20. Claims 3 and 4 remain objected to as dependent on rejected base claims.

Conclusion

21. Claims 1, 2, 5-14, 17-24 and 27-29 are rejected, and claims 3 and 4 are objected to.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Coppins whose telephone number is 571.272.0680. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's acting supervisor, Joseph McKane can be reached on 571.272.0699. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Janet L. Coppins
February 7, 2004

RDesai

for Joseph McKane, acting SPE
Art Unit 1625